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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,740	<b>Applicant(s)</b> MACGREGOR, ALEXANDER	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 14-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-12,14-21 and 24-33 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of amendment to the specification and to the claims and remarks, all filed 12/16/03. Claims 1, 3-12 and 14-33 are pending.

#### *Priority*

The claim to priority of provisional application number 60/251,751 is acknowledged.

#### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 14-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of amendment to claims 14 and 18.
2. However claims 12, 17, 20, 24, 29 and 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 17 recites the limitation "said polyglucan" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "polyglucan" and thus does not provide antecedence for "polyglucan."
4. Claim 20 recites the limitation "said rapidly swelling" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "rapidly swelling."
5. Claim 24 recites the limitation "the dosage" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "dosage."
6. Claims 29 and 30 recite "matrix-type" and the type makes the claims indefinite. See Copenhaver, POBA, 1955, 109 USPQ 118-119.

Art Unit: 1615

7. Claim 12 does not end with a period. A claim begins with a capital letter and ends with a period.

Correction is respectfully requested.

***Claim Rejections - 35 USC § 102***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 3, 5, 24 and 33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fritsch et al. (US 5,213,794).

Fritsch discloses a tablet formulation that comprises polyacrylic acid/methacrylate copolymer, polyvinylpyrrolidone, propylene glycol, calcium polycarbophil, crospovidone, silica, saccharin sodium, banana flavoring and calcium stearate (example 1 and column 6, lines 34-53). The combination of polyvinylpyrrolidone and the acrylate polymer is equivalent to the hydrostatic couple of the instant claims. The active ingredient in Fritsch is antacid (abstract and examples 1 and 2). The swelling capacity recited in claim 3 is a property of the polymer and since the property of a compound or formulation cannot be separated from the compound or formulation, the formulation of Fritsch would inherently have the properties recited in claim 3. The teachings of Fritsch meet the limitation of the claims.

Applicant argues that

- a) Fritsch does not disclose a hydrostatic delivery system designed to produce a steady state efflux or a controlled release of the agent of interest over a period of time.
- b) Fritsch does not disclose using a cross-linked hydrostatic pressure-modulating agent.

Art Unit: 1615

c) Fritsch does not disclose a hydrostatic delivery system that releases an agent of interest at a rate that is substantially concentration independent.

10. Applicant's arguments filed 12/16/03 have been fully considered but they are not persuasive.

On count a) it is noted that Fritsch discloses a hydrostatic delivery system and the production of a steady state efflux or controlled release of the agent of the interest is an inherent property of the delivery system.

On count b) it is noted that Fritsch discloses a crosslinked polymer because crospovidone is a crosslinked polyvinylpyrrolidone and a hydrostatic pressure-modulating agent comprises a hydrophilic cross-linked polymer.

On count c) it is noted that the hydrostatic delivery system of Fritsch would inherently release an agent of interest at a rate that is substantially concentration independent.

Thus, Fritsch discloses the instant delivery system.

11. It is also respectfully noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

*Applicant is respectfully requested to address the Cook et al. anticipatory or lack of anticipatory argument raised in the remarks and argument.*

Art Unit: 1615

12. Claims 1, 3, 5, 7, 8, 11, 12, 14, 15, 18, 20, 21, 24-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rork et al. (US 5,582,838).

Rork discloses a tablet formulation (column 7, lines 21-42) comprising pharmaceutically active ingredients such as antimicrobials, local anesthetic, analgesics and anti-inflammatory agents (column 6, lines 18, 20, 24 and 18), excipients such as lactose, magnesium stearate, polyvinylpyrrolidone and dyes (column 8, lines 13-25), CARBOPOL polymer (column 8, lines 45-65) and carbonate (claims 10), and the formulation is coated (abstract). See also column 13, line 20 to column 14, line 9). The combination of the CARBOPOL and the polyvinylpyrrolidone constitutes the hydrostatic couple of the instant application. The carbonate is the carbon dioxide precursor of the instant application. Rork teaches particulate formulation (column 8, lines 21-25) and the pharmaceutically active agents are present in amounts of from about 0.01% to about 75% of the core weight (column 8, lines 26-32). Regarding claims 3 and 5, the formulation of Rork would inherently have the recited property. Regarding claim 15, which depends back to claim 2, it is noted that there is no specific amount of the acrylic polymer recited in claim 2, and thus, the acrylic polymer of the prior art would inherently have the same viscosity if the viscosity measurement is conducted on a 0.5% of the polymer of the prior art. The teachings of Rork meet the limitations of the claims.

Applicant argues that

- a) Rork does not disclose a hydrostatic delivery system designed to release an agent of interest at a rate that is substantially concentration independent.
- b) Rork does not disclose a crosslinked polyvinylpyrrolidone and thus does not disclose a hydrostatic pressure-modulating agent.

Art Unit: 1615

13. Applicant's arguments filed 12/16/03 have been fully considered but they are not persuasive.

On count a) it is noted that Rork discloses a hydrostatic delivery system and it is noted that the hydrostatic delivery system of Rork would inherently release an agent of interest at a rate that is substantially concentration independent

On count b) it is noted that Rork discloses cross-linked polymer because CARBOPOL 934P and CARBOPOL 974P are cross-linked and the requirement of instant claim 12 is either cross-linked polyvinylpyrrolidone or cross-linked cellulose derivative. The generic claim 1 requires a cross-linked polymer. Therefore, because, Rork discloses a cross-linked polymer, Rork discloses a hydrostatic pressure-modulating agent. Thus, Rork discloses the instant delivery system.

*Applicant is respectfully requested to address the Cook et al. anticipatory or lack of anticipatory argument raised in the remarks and argument.*

***Claim Rejections - 35 USC § 103***

14. Claims 4, 6, 9, 10, 16 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838).

Rork teaches the tablet formulation of the invention except that Rork fails to teach the amounts of the polymers. However, since the hydrostatic couple may determine the swelling capability of the polymer (see column 1, lines 22-32 of Rork), one having ordinary skill in the art would adjust the amounts the polymer to achieve the desired swelling for the desired drug delivery. Regarding claim 10, one of ordinary skill in the art has the ability to determine how much carbonate would be required for expansion of the dosage form for the release of actives.

Art Unit: 1615

Applicant has no comparable example to demonstrate that the particle size recited in claims 19 and 16 provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet formulation that comprises nifedipine and the hydrostatic couple of polyvinylpyrrolidone and CARBOPOL according to the teachings of Rork. One having ordinary skill in the art would have been motivated to use appropriate amount of the CARBOPOL with the expectation of achieving the desired delivery.

Applicant argues that there would be no motivation to have the teachings of Rork modified because Rork does not teach or suggest the instant hydrostatic delivery system. However, this argument is not persuasive because as pointed out above, Rork discloses hydrostatic delivery system. Obviousness rejection is provided on the basis of amounts of the cross-linked polymer and not on disclosure of the cross-linked polymer.

Applicant further argues that a modification of Rork will not lead to the instant delivery system. This argument is also not persuasive, because when the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

*Applicant is respectfully requested to address the Cook et al. anticipatory or lack of anticipatory argument raised in the remarks and argument.*

15. Claims 22 and 23 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art, Rork and Fritsch do not disclose oxygen precursor and chlorine dioxide precursor.



Art Unit: 1615

16. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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